10. (Amended) The apparatus as recited in claim 8, wherein the analyzer unit includes a memory for storing a pressure pulse characteristic signal of a proper vascular access and a central processor for comparing [a measured pressure pulse signal] the second pressure pulses waveform with the pressure pulse characteristic signal, and for detecting a faulty vascular access upon a certain signal deviation.

REMARKS

Reconsideration and allowance of the captioned application is respectfully requested. Applicants have amended claims 1, 2, 8 and 10. Claims 1-14 are pending.

In the Office Action the Examiner rejected claims 1 to 14 under 35 U.S.C. § 103 as being unpatentable over European Patent Application No. 611,228 in view of German Patent No. 4,239,937 and European Patent Application No. 332,330.

Applicants respectfully disagree with the rejection. EP '228 describes a technique for extracorporeal treatment of blood, using a third pressure sensor 54 to monitor the pressure level and determine if return line 35 or return catheter 36 are disconnected or leaking. (Col 7, lines 25-28.) An alarm is triggered if a monitor processor 140 receives signals from third pressure sensor 54 that the pressure in return line 35 is less than a predetermined value stored in memory 142, thus indicating a disconnection of the patient's return catheter. (Col. 24, lines 25-31.) Third pressure sensor 54 is located in the return line of the extracorporeal blood circuit, as shown in Fig. 1 of EP '228.

EP '228 thus discloses measuring a pressure value in the blood return line, and signaling an alarm if that measured pressure falls below a predetermined value of pressure stored in memory. EP '228 does not disclose monitoring a waveform of a pressure pulse propagating in the extracorporeal blood circulation path, and comparing that waveform to determine a characteristic change in the waveform, as recited in claims 1 and 8. EP '228 also does not describe generating pressure pulses with a pressure pulse generator disposed in the dialysis fluid path, such that

pressure pulses in the extracorporeal blood circulation path are induced. Instead, EP '228 describes simply monitoring the pressure in the blood circulation path.

GP '937 describes an ultrafiltration dialysis function testing. This device tests the operation of an ultrafiltration system, not the integrity of the vascular access, as done in EP '228. Accordingly, one of ordinary skill in the art would not have been motivated to combine this reference with EP '228, to obtain the claimed method and device for monitoring vascular access.

Even if the combination of these references was proper, the addition of GP '937 to the other cited references would not render the claimed invention obvious. GP '937 describes testing for correct operation of the hemodialysis system that includes disconnecting dialysator 1 from the dialysis fluid circuit II, and performing a pressure holding test by comparing the value measured by pressure pick-up 22 with a value in a stable condition. (Dialog Translation of the Abstract, Page 1.)

Thus, GP '937 describes separating the blood circulation path from the dialysis fluid path while performing the test, and measuring the pressure with sensor 22, located in the dialysis fluid path. (See Fig. 1.) This is different from generating pressure pulses in the dialysis fluid path, and monitoring the induced pulse waveforms in the blood circulation path, as recited in claims 1 and 8. Accordingly, GP '937 does not provide the elements missing from EP '228 to render the claimed invention obvious.

EP '330 describes an infiltration detection system and method, used in an infusion system. This reference not only does not address hemodialysis, but also does not address the problem of faulty vascular access. Instead, EP '330 is concerned with preventing injection of a medication outside of a vascular channel. Accordingly, one of ordinary skill in the art would not be motivated to combine EP '330 with the other references cited by the Examiner.

Even if such combination of references was permissible, the addition of EP '330 to the other references would not render claims 1 and 8 obvious. EP '330 describes a single fluid path for providing a medication to a patient. (See Fig. 1.) EP '330 does not describe a separate blood circulation path and dialysis fluid path, thus cannot describe generating pressure pulses in the dialysis fluid path, and monitoring the induced pulse waveforms in the blood circulation path, as recited in claims 1 and 8. In addition, EP '330 describes generating a test pulse that is

different from the pulses in the normal delivery pattern. (Page 3, lines 45-48.) This is different from the claimed system where the waveforms are generated during the normal operation of the system.

Accordingly, EP '330 does not render claims 1 and 8 obvious, even in combination with the other cited references. Claims 1 and 8 are therefore allowable. Claims 2-7 and 9-14 depend from claims 1 or 8, and at least for that reason are also allowable.

CONCLUSION

Applicants believe that this application is in condition for allowance, and such action is respectfully requested. If for any reason the Examiner believes that contact with Applicant's attorney would advance prosecution, the Examiner is invited to contact the undersigned at the telephone number given below. The Office is authorized to charge any fees associated with this Amendment, including those under 37 C.F.R. §§ 1.16 or 1.17, to Deposit Account No. 11-0600.

Respectfully submitted,

Dated: January 11, 2000

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